

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Adrian Gilbert et al. Examiner: A. DeCloux  
 U.S. Serial No.: 09/788,131 Group Art Unit: 1604  
 Filed : February 16, 2001  
 For : ORAL, NASAL AND PULMONARY DOSAGE  
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1185 Avenue of the Americas  
 New York, New York 10036  
 August 1, 2002

Assistant Commissioner for Patents  
 Washington, D.C. 20231

SIR:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
PURSUANT TO 37 C.F.R. §1.97(b)(3)

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following publications which are listed again on the attached Form PTO-1449 (**Exhibit A**) and copies of References Items 1-35 (**Exhibits 1-32**) are enclosed.

This Supplemental Information Disclosure Statement is being submitted before the issuance of a first Office Action on the merits in connection with the subject application. Accordingly, no fee is required and this Supplemental Information Disclosure Statement shall be considered pursuant to 37 C.F.R. §1.97(b)(3).

Applicants also point out that several of the listed references are counterparts of each other and are cumulative. Therefore, in accordance with 37 C.F.R. § 1.98(c), a counterpart of a reference is identified after the cite to the reference, but a copy of only one of the counterparts is being provided. Upon request, applicants will provide the Examiner with copies of any reference that is reasonably available to them.

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1. U.S. Patent No. 5,554,372, issued September 10, 1996 (Hunter et al.) (**Exhibit 1**);
2. U.S. Patent No. 5,623,052, issued April 22, 1997 (McLean et al.) (**Exhibit 2**);
3. U.S. Patent No. 5,734,023, issued March 31, 1998 (Bishwajit et al.) (**Exhibit 3**);
4. U.S. Patent No. 5,886,156, issued March 23, 1999 (McLean et al.) (**Exhibit 4**);
5. U.S. Serial No. 09/487,793, filed January 20, 2000 (**Exhibit 5**);
6. U.S. Serial No. 09/620,216, filed July 20, 2000 (**Exhibit 6**);
7. U.S. Serial No. 09/765,301. Applicants point out that this reference is a counterpart of PCT International Application No. PCT/US01/02118 (WO 01/93893) (**Exhibit 12**);
8. U.S. Serial No. 09/765,644. Applicants point out that this reference is a counterpart of PCT International Application No. PCT/US01/02117 (WO 01/52878) (**Exhibit 11**);
9. PCT International Application No. PCT/EP91/01420 (WO 92/02543), published February 20, 1992 (Gaeta et al.) (**Exhibit 7**);
10. PCT International Application No. PCT/US93/06249 (WO

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- 94/03484), published February 17, 1994 (McLean et al.). Applicants point out that this reference is a counterpart of U.S. Patent No. 5,623,052 (Exhibit 2) and U.S. Patent No. 5,886,156 (Exhibit 4);
11. PCT International Application No. PCT/US94/05632 (WO 94/26774), published November 24, 1994 (Alexander et al.) (**Exhibit 8**);
  12. PCT International Application No. PCT/US95/04121 (WO 95/26980), published October 12, 1995 (Hackett et al.) (**Exhibit 9**);
  13. PCT International Application No. PCT/US94/05697 (WO 95/31997), published November 30, 1995 (Reid et al.) (**Exhibit 10**);
  14. PCT International Application No. PCT/US01/02117 (WO 01/52878), published July 26, 2001 (Eisenbach-Schwartz et al.) (**Exhibit 11**);
  15. PCT International Application No. PCT/US01/02118 (WO 01/93893), published December 13, 2001 (Eisenbach-Schwartz et al.) (**Exhibit 12**);
  16. Henry, Celia M., "Special Delivery", Chem. and Eng. News, Sept. 18, 2000, 49-54 (**Exhibit 13**);
  17. Cohen, "Fundamental Immunology", Systemic Autoimmunity, 4<sup>th</sup> Ed., 1999, 1083 (**Exhibit 14**);
  18. Fridkis-Hareli et al., "Binding of random copolymers of three amino acids to class II MHC molecules", Intl.

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Immunol., 1999, 11(5): 635-641 (**Exhibit 15**);

19. Li et al., "Glatiramer acetate blocks the activation of THP-1 cells by interferon- $\gamma$ ", Eur. J. Pharmacol., 1998, 342: 303-310 (**Exhibit 16**);
20. Zisman et al., "Dichotomy between the T and the B cell epitopes of the synthetic polypeptide (T,G)-A--L", Eur. J. Immunol., 1994, 24(10): 2497-2505 (Abstract) (**Exhibit 17**);
21. Deeb et al., "Comparision of Freund's and Ribi adjuvants for inducing antibodies to the synthetic antigen (TG)-AL in rabbits", J. Immunol. Methods, 1992, 152(1): 105-113 (Abstract) (**Exhibit 18**);
22. Zisman et al., "Direct binding of a synthetic multichain polypeptide to Class II Major Histocompatibility Complex molecules on Antigen-Presenting Cells and stimulation of a specific T-cell line require processing of the polypeptide", Proc. Natl. Acad. Sci. USA, 1991, 88(21): 9732-9742 (Abstract) (**Exhibit 19**);
23. Matsunaga et al., "Complementation of Class II A alleles in the immune response to (Glu-Lys-Tyr) polymers", Yokohama Med. Bull., 1988, 39(1-2): 9-19 (Abstract) (**Exhibit 20**);
24. De Kruyff et al., "Analysis of T Cell Responses to Poly-L (GluLys) at the Clonal Level. I. Presence of Responsive Clones in Nonresponder Mice", Eur. J. Immunol., 1987, 17(8): 1115-1120 (Abstract) (**Exhibit 21**);
25. Lai et al., "Complementation of Class II A alleles in the

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- immune response to (GluLysTyr) polymers", Exp. Clin. Immunogenet., 1986, 3(1): 38-48 (Abstract) (**Exhibit 22**);
26. Lai et al., "Monoclonal T cell responses to two epitopes on a single immunogen controlled by two distinct genes", J. Immunol., 1986, 136(10): 3799-3804 (Abstract) (**Exhibit 23**);
27. Trannoy et al., "Epitope-specific regulation of the T cell repertoire: carrier recognition in association with I-E or I-A does not influence the restriction of hapten-specific T cells", Eur. J. Immunol., 1985, 15(12): 1215-1221 (Abstract) (**Exhibit 24**);
28. Falo et al., "Analysis of antigen presentation by metabolically inactive accessory cells and their isolated membranes", Proc. Natl. Acad. Sci. USA, 1985, 82(19): 6647-6651 (Abstract) (**Exhibit 25**);
29. Babu et al., "Ir gene control of T and B Cell Responses to Determinants in (Glu Lys Ala) Terpolymer", J. Immunogenet., 1984, 11(3-4): 251-254 (**Exhibit 26**);
30. Babu et al., "Reevaluation of response patterns of nonresponder mice to GLPhe polymers", Immunogen., 1983, 18(1): 97-100 (Abstract) (**Exhibit 27**);
31. Herzenberg et al., "Lack of immune response gene control for induction of epitope-specific suppression by TGAL antigen", Nature, 1982, 295: 329-331 (Abstract) (**Exhibit 28**);
32. Baxevanis et al., "Genetic Control of T-Cell Proliferative Responses to Poly (Glu<sup>40</sup>Ala<sup>60</sup>) and Poly (Glu<sup>51</sup>Lys<sup>34</sup>Tyr<sup>15</sup>):

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Subregion-Specific Inhibition of the Responses with Monoclonal Ia Antibodies", Immunogenetics, 1980, 11: 617-628 (**Exhibit 29**);

33. Maurer et al., "Interpretations of immune responses of mice to poly(Glu60Lys40), its modified derivatives, and the terpolymers poly (Glu55Lys37Leu8) and poly (Glu56Lys37Ser7)", Clin. Immunol. Immunopathol., 1980, 15(3): 344-356 (Abstract) (**Exhibit 30**);
34. Ju et al., "Idiotypic analysis of antibodies against the terpolymer L-glutamic acid 60-L-alanine30-L-tyrosine10 (GAT). IV. Induction of CGAT idiotypic following immunization with various synthetic polymers containing glutamic acid and tyrosine", Eur. J. Immunol., 1979, 9(7): 553-560 (Abstract) (**Exhibit 31**); and
35. Schwartz et al., "Gene complementation in the T lymphocyte proliferative response to poly (Glu57Lys38Tyr5): Evidence for effects of polymer handling and gene dosage", J. Immunol., 1979, 123(1): 272-278 (Abstract) (**Exhibit 32**).

Applicants request that the Examiner review the publications and make them of record in the subject application.

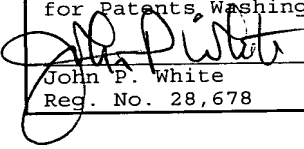
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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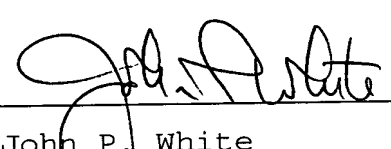
No fee is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if any fee is required, authorization is hereby give to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231

  
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8/1/02  
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